JAN 1 8 2002

510(k) Summary

Biliary and Pancreatic Stents

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92

Device Name:	Biliary and Pancreatic Stents
Common/Usual Name:	Biliary and Pancreatic Duct Endoprosthesis
Classification name:	Class II; Gastro-Urology Device Panel; CFR 876-5010, Product Code: FGE
Proprietary Name:	Various Brand Names of Biliary and Pancreatic Stents
Predicate Devices:	Stents manufactured by Olympus, Wilson-Cook and Microvasive
Prepared and submitted by:	Scott Karler Regulatory Coordinator Medi-Globe Corporation 6202 S. Maple Avenue, Suite 131 Tempe, Arizona 85283 (480) 897-2772
Preparation Date:	January 17, 2001
Indications for Use:	The Medi-Globe/GIP Biliary and Pancreatic Stents are intended to be passed through an endoscope and used as an aid in transpapilliary drainage of obstructed ducts within the biliary and pancreatic trees.
Substantial Equivalence:	This device is manufactured according to specified processes and quality Assurance Programs. The device will undergo packaging and sterilization procedures similar to those devices currently manufactured and marketed by Medi-Globe/GIP. This device is similar with respect to indications for use, design and safety and effectiveness to the stents manufactured by Olympus, Wilson-Cook and Microvasive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Mr. Scott Karler
Regulatory Coordinator
Medi-Globe® Corporation
6202 S. Maple Avenue, #131
TEMPE AZ 85283

Re: K010549
Trade/Device Name: Medi-Globe®/GIP Biliary and Pancreatic Stent and Stent Set/Kit
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: October 16, 2001
Received: October 22, 2001

Dear Mr. Karler:

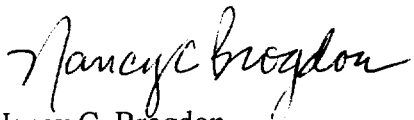
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010549

Device Name: Medi-Globe/GIP Biliary and Pancreatic Stent and Stent Set/Kit

Indications For Use:

The Medi-Globe/GIP Biliary and Pancreatic Stent and Stent Set/Kit is intended to aid in transpapilliary drainage of obstructed ducts within the biliary and pancreatic trees.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010549

Prescription Use ✓